REMARKS

This paper is responsive to the non-final Office Action mailed on November 2, 2006. Applicants have not amended any of the claims at this time. Claims 12-33 remain pending.

In the Office Action, the Examiner rejected claims 12-32 under 35 U.S.C. 103(a) as being unpatentable over Mangram et al. (Guideline for prevention of surgical site infection) ("Mangram") in view of Ormond-Walshe, Sarah (Computerized databases in infection control) (Ormond-Walshe) and further in view of Blume (US 6,157,853) and Mushabac (US 5,562,448). Applicants respectfully traverse the rejections. The applied references fail to disclose or suggest the inventions defined by Applicants' claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Applicants' pending claims concern computer-implemented techniques and systems for managing risks of surgical site infection in a surgical procedure. In particular, claim 12 recites a computer-implemented system for managing the risk or occurrence of surgical site infection incident to a surgical procedure. The computer-implemented system of claim 12 comprises software that identifies a plurality of stages of operative care associated with the surgical procedure, including at least a preoperative stage, an intraoperative stage and a postoperative stage. The software also identifies one or more points-of-care within each identified stage of operative care associated with the surgical procedure, and for each point-of-care associated with the surgical procedure, identifies one or a plurality of health care delivery practices associated with the surgical procedure that pose a source of measurable risk of surgical site infection, and identifies one or more compliance indicators associated with the surgical procedure for one or a plurality of health care practices associated with the surgical procedure within each point-of-care associated with the surgical procedure whereby there is provided the ability to monitor the compliance indicators. For each of the compliance indicators, the software generates a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby align the health care delivery practices associated with the surgical procedure into rule compliance and to provide a perioperative process map of delivery practices spanning the plurality of stages of operative care associated with the surgical procedure to thereby manage the risk or occurrence of surgical site infection incident to the surgical procedure.

Claim 13 recites a system for managing the risk or occurrence of surgical site infection incident to a surgical procedure, the system comprising a perioperative process map of practices for the delivery of the surgical procedure, the map comprising a plurality of health care delivery practices associated with the surgical procedure and one or more indicators of compliance with the one or more health care practices, and means for monitoring the compliance indicators to achieve a desired level of management of the risk of surgical site infection for the surgical procedure, wherein the means for monitoring the compliance indicators generates a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure.

Claim 22 recites a computer-implemented method for managing risks of surgical site infection incident to a surgical procedure, the method comprising evaluating a practice associated with the surgical procedure that poses an infection risk during a stage of the surgical procedure, storing data indicative of the practice associated with the surgical procedure as executed by one or more persons involved with the surgical procedure, and identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage risks of surgical site infection incident to the surgical procedure.

In the Office Action, the Examiner cited Mangram as teaching techniques for managing risks of surgical site infection in a surgical procedure. The Examiner recognized that Mangram fails to suggest a computer-implemented system for managing such risks, but cited Ormond-Walshe as teaching the use of computerized databases in the medical field. The Examiner argued that a person of ordinary skill in the art would have been motivated to implement the computerized databases of Ormond-Walshe to manage the risks of surgical site infection taught by Mangram.

At this point in the analysis, the Examiner recognized that the combination of Mangram and Ormond-Walshe still fails to disclose or suggest generating a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule (claims 12 and 13) or identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice (claim 22). However, the Examiner stated that this feature is well known in the art as evidenced by Blume and Mushabac.

Applicants respectfully traverse the rejections. Nothing in Blume, Mushabac or any of the applied references discloses or suggests computer-implemented techniques that generate a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13) or techniques that identify when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claim 22). Moreover, a person of ordinary skill in the art would not have been motivated to implement the techniques or devices of Blume and/or Mushabac with the teaching of Mangram or Ormond-Walshe.

The entire passage of Bloom relied upon by the Examiner is reproduced below:

> Data received from localizers 20, and the processing by processor 32 to present a graphical representation on display 40 of the magnetic field produced by magnet 14 must be fast enough to provide "real-time" feedback for a surgeon; i.e., the feedback must be rapid enough to allow decisions to be made during a surgical procedure involving the movement of the implanted magnetic device 30. The method of Procrustes is used to compute the 4.times.4 rigid body transformation between coordinates in the imaging system and coordinates in the localizer system. Thereafter, the 4.times.4 matrix may be applied to transform a pre-stored representation of a magnetic field into a magnetic field having the position and orientation sensed by localizers 20 using standard programming techniques on a presently-available Intel PENTIUM.RTM.-based processor (such as a typical PC), or a Silicon Graphics workstation, with the transformation being accomplished in sufficient time to provide a display that is updated rapidly enough for surgical purposes. Column 7, lines 16-33.

Contrary to the Examiner's conclusion, this teaching in Bloom has no relevance with respect to the features recited in Applicants claims, which concern computer-implemented systems for managing the risk or occurrence of surgical site infection. In contrast to Applicants' claims, this teaching of Bloom describes the use of magnets in a surgical procedure to provide the surgeon with positioning feedback via a display regarding the positioning and movement of an implanted magnetic device. Thus, this teaching of Bloom has no relevance to computer-implemented systems for managing the risk or occurrence of surgical site infection, and lacks any teaching pertinent to such endeavors.

Furthermore, the teaching of Bloom cited above clearly lacks any suggestion of

generating a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13) or identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claim 22).

Similarly, the teaching of Mushabac relied upon by the Examiner is also irrelevant to the features of Applicants' claims. The relied upon passage of Mushabac is reproduced below.

> Advantageously, the computer provides the dental practitioner operating the dental tool with an alert signal regarding deviation between an actual position and orientation of the tool during the use of the tool on the patient and the optimal position and the optimal orientation, as determined prior to the dental operation. The alert signal may take the form of an auditory signal, for example, a verbal message or instruction synthesized by the computer. Alternatively or additionally, the alert signal may include a visual indication provided on the monitor. An alert signal may also be provided in a practice operation, to indicate to the operator a deviation or a conformity of the practice instrument to the predetermined, recommended position and orientation thereof. Column 4, lines 56 to column 5, line 2.

This passage of Mushabac also lacks any relevance to computer-implemented systems for managing the risk or occurrence of surgical site infection. Instead, this passage of Mushabac describes a dental tool that generates an audible or visible alert when the dental tool is mis-positioned.

An alert that is generated when a dental tool is mis-positioned is nothing akin to the features of Applicants' claims, e.g., generating a flag when a given health care practice associated with the surgical procedure is not in compliance with a rule to thereby manage the risk of surgical site infection incident to the surgical procedure (claims 12 and 13) or identifying when the data indicative of the practice associated with the surgical procedure is not in compliance with a rule established for the practice to thereby manage the risk of surgical site infection incident to the surgical procedure (claim 22). A person of ordinary skill in the art would not have found any teaching in Mushabac or Bloom that would have led the person to modify a computer-implemented system for managing the risk or occurrence of surgical site infection to generate a flag when a surgical procedure is not in compliance with a rule.

Indeed, the teaching of Bloom and Mushabac are completely unrelated to that of Mangram and Ormond-Walshe. Accordingly, a person of ordinary skill in the art would have found no reason to modify the teachings of Mangram and Ormond-Walshe in view of Mushabac and Bloom. To be sure, Bloom describes a system that provides a surgeon with positioning feedback via a display regarding the positioning and movement of an implanted magnetic device, and Mushabac describes a dental tool that generates an alert when the tool is mis-positioned. These teachings concern totally different endeavors than those of Mangram and Ormond-Walshe and include no teachings pertinent to the management of infection in surgical procedures.

Furthermore, even if the alert generation in Mushabac could be reasonably construed as generating a flag, the alert in Mushabac occurs when a dental tool becomes misaligned, and has no relevance to compliance of a surgical procedure with a rule, nor any relevance to the management of risks of surgical site infection incident to the surgical procedure.

In addition, Applicants also dispute the Examiner's more basic conclusion that a person of ordinary skill in the art would have modified the teaching of Mangram in view of Ormond-Walshe to implement compliance indicators associated with the surgical procedure for one or a plurality of health care practices associated with the surgical procedure. Applicants also disputed this conclusion in the previous response, but the Examiner failed to address these arguments, stating that Applicants' arguments were moot in view of the new ground of rejection. The arguments below, however, which were also advanced in the previous response, are still fully applicable to the current rejections insofar as the current rejections still rely on an incorrect conclusion that a person of ordinary skill in the art would have been motivated to modify the teaching of Mangram in view of Ormond-Walshe.

While Mangram may provide a manual guideline for prevention of surgical site infection, this reference lacks any suggestion of compliance indicators associated with the surgical procedure for one or a plurality of health care practices associated with the surgical procedure whereby there is provided the ability to monitor the compliance indicators. Moreover, the vague teaching of Ormond-Walshe concerning the use of computerized databases would have provided no additional insight to a person of ordinary skill in the art regarding the implementation of compliance indicators associated with the surgical procedure. In particular, the broad general discussion of computerized databases for use by infection nurses, per Ormond-Walshe, provides

no insight to the specific implementation of compliance indicators associated with the surgical procedure, as recited e.g., in claims 12 and 13.

In short, Applicants dispute the Examiner's conclusion that a person of ordinary skill in the art would have been motivated to combine the teaching of Mangram and Ormond-Walshe to implement compliance indicators. Neither Mangram nor Ormond-Walshe (either alone or in combination) disclose or suggests this feature.

In addition, neither Mushabac nor Bloom discloses or suggests computerized generation of a flag or identification of data associated with a surgical procedure to thereby manage the risk of surgical site infection incident to the surgical procedure. To the extent that Mushabac teaches the generation of an alert, the alert in of Mushabac relates to dental tool misalignment, and has no relevance to a surgical procedure, nor any relevance to the management of risks of surgical site infection incident to the surgical procedure. Furthermore, a person of ordinary skill in the art would have found no reason to modify the teachings of Mangram and Ormond-Walshe in view of Mushabac or Bloom. Indeed, positioning of implanted magnetic devices, per Bloom, and dental tools that generate alerts when the tools are mis-positioned, per Mushabac are not reasonably pertinent to the teachings of Mangram concerning prevention of surgical site infection, nor reasonably pertinent to the teaching of Ormond-Walshe concerning computerized databases for infection control. For each of these reasons, the current rejections must be withdrawn.

In view of the foregoing comments, Applicants respectfully request the Examiner's reconsideration and prompt allowance of all pending claims. In view of the distinctions addressed above between the current claims and the applied prior art, Applicants reserve further comment at this time on any other features of the independent or dependent claims. However, Applicants do not necessarily acquiesce in any of the rejections or the Examiner interpretations of the applied references. Applicants reserve the right to present additional arguments with respect to any of the independent or dependent claims.

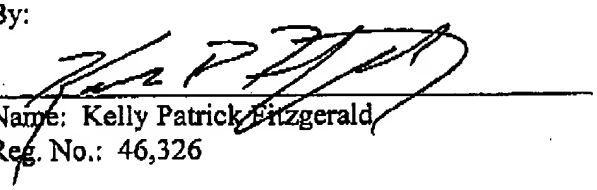
Application Number 09/729,034
Responsive to Office Action mailed November 2, 2006

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

January 23, 2007

By:



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